medroxyprogesterone acetate (MPA) in Familial Adenomatous Polyposis, a proof of principle study

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To assess in a cohort of patients with established FAP:1 The efficacy of MPA in terms of reduction of number of colonic polyps, by means of Endoscopic Appearance of Polyposis (EAP) index.2 The effect on histological parameters and biological...

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON31609

Source
ToetsingOnline

Brief title
MPA in FAP

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
familial adenomatous polyposis (FAP), familial polyposis

Research involving
Human

Sponsors and support

Primary sponsor: maag darm leverziekten
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colon cancer, familial adenomatous polyposis, medroxyprogesterone acetaat

Outcome measures

Primary outcome

Change in adenoma number or density.

Secondary outcome

Changes in biological and histological parameters.

Study description

Background summary

The use of progestins in combination with estrogen is associated with a reduced incidence of colorectal carcinoma (CRC). Also, incidental literature has reported a coincidence of the start of oral contraceptive agents with reduction in polyp number in a girl with Familial Adenomatous Polyposis (FAP)3. In this study we test the hypothesis that progestins may reduce reduction polyp burden in patients with Familial Adenomatous Polyposis (FAP), a familial polyposis syndrome.

Study objective

To assess in a cohort of patients with established FAP:
1 The efficacy of MPA in terms of reduction of number of colonic polyps, by means of Endoscopic Appearance of Polyposis (EAP) index.
2 The effect on histological parameters and biological response of MPA medication.

Study design

This is an open label, proof-of-principle study in which 10 female patients will receive MPA (Provera, Pfizer BV) 10 mg/day orally for 4 months. At baseline and four months patients will undergo colonoscopy, with video recording and taking of biopsies. Videos will be assessed for Endoscopic Appearance of Polyposis (EAP) index by an expert panel of gastroenterologists. Biopsies will be assessed for cell proliferation, apoptosis and targets of progesterone signaling.

Intervention

All patients receive MPA (Provera, Pfizer BV) in a daily dosage of 10 mg for four months.

Study burden and risks

Two colonoscopies will be performed. This is usually regarded as having a low burden. With a colonoscopy there is a small risk for complications (0.1%). These are generally treated by admitting and observing the patient for a short time. Treatment with MPA carries smalli risks as discribed in the medication folder.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

• Females > 14 years of age
• Established FAP, confirmed by prior colonoscopy
• Patients must be able to adhere to the study visits and protocol requirements
• Patients must be able to give written informed consent. In case of a minor, parents/legal representative must be able to give a written consent. The consent must be obtained prior to any screening procedures

Exclusion criteria

• Prior progestin use in the past year
• Change in the use of NSAIDs at least 3 month prior to the study
• Allergic reaction on MPA during previous use
• Female patients who are pregnant or breast-feeding.
• Prior thromboflebitis or thromboembolism.
• Previous or current serious cardiac or cerebrovascular condition. Like thromboflebitis or thromboembolism, severe hypertension, severe liverfunction disorders. A history of jaundice, herpes gestationis non-explained vaginal bleeding or deterioration of otosclerosis during pregnancy or use of female hormones.
• Male and female patients with fertility wish for the study period
• Not available for follow-up assessment

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	10

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	provera
Generic name:	medroxyprogesterone acetate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-06-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-007477-23-NL
CCMO	NL21328.058.08